



JUN 17 1996

K961055

GE Medical Systems

General Electric Company  
P.O. Box 414, Milwaukee, WI 53201

**Summary of Safety & Effectiveness**  
**15 March 1996**

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR Part 807.87(h).

**Contact:** Larry Kroger  
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**Product Identification:**

**Name:** CT ProSpeed CT/i  
**Manufacturer:** GE - Yokogawa Medical Systems  
7-127 Asahigaoka, Hino-shi  
4-chome, Tokyo 191, Japan  
**Distributor:** GE Medical Systems  
3000 N. Grandview  
Waukesha, WI 53188

**Indications for Use:**

The CT ProSpeed CT/i is indicated for head and whole body x-ray computed tomography applications. It provides axial, helical and scout imaging.

**Device Description:**

The device is an x-ray computed tomography scanner consisting of a gantry, patient table, console, computer, and associated accessories.

**Materials:** Materials and construction are equivalent to the CT ProSpeed Plus and are compliant with UL 187, IEC 601-1, and 21 CFR Subchapter J.

**Design:** The design is essentially the same as the CT ProSpeed with HiLight Detector (K944013) the difference being that it uses a computer workstation user interface similar to our HiSpeed CT/i (K 940606).

**Energy Source and Exposure Levels:** The energy source is can be over the range of 208 to 480 Vac 50/60 Hz.

- 3.5MHU tube capacity,
- high frequency on-board generator
- 42kW output power
- CTDI at 120kVp, 300 mAs, 1s scan for body, 1.5 s scan for head, 10mm aperture:

Center : Head 60 mGy (6.0 Rad) Body 17 mGy  
(1.7 Rad)

Surface: Head 62 mGy (6.2 Rad) Body 31 mGy  
(3.2 Rad)

**Marketing History:**

It is the opinion of GE Medical Systems that the ProSpeed CT/i is of a comparable type and substantially equivalent to currently marketed head and whole body x-ray computed tomography systems.

**Adverse Effects on Health:**

Potential electrical, mechanical and radiation hazards are identified in a hazard analysis and controlled by:

- Failure Mode Effects Analysis to demonstrate the non-existence or extremely low probability of unwanted events.
- System evaluation to insure performance to specifications and Federal Regulations.
- Adherence to Industry and International Standards. (UL and IEC)

**Conclusions:**

Use of the ProSpeed CT/i does not result in any new potential safety risks.